

PART 1232—CARE AND USE OF ANIMALS IN THE CONDUCT OF NASA ACTIVITIES

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AUTHORITY: 42 U.S.C. Sec. 2451; Pub. L. 89-544, as amended; 7 U.S.C. Sec. 2131; 39 U.S.C. Sec. 3001; 9 CFR subchapter A parts 1, 2, 3, and 4; and Pub. L. 99-158, Sec. 495.

SOURCE: 54 FR 35870, Aug. 30, 1989, unless otherwise noted.

§ 1232.100 Scope.

This rule establishes the policy, implementation procedures, and management authority and responsibility for the care and use of vertebrate animals (hereinafter referred to as "animal subjects") in the conduct of NASA activities.

§ 1232.101 Applicability.

This rule applies to NASA Headquarters and NASA field installations and will be followed in all activities using animal subjects that are supported by NASA, conducted in NASA facilities, aircraft, or spacecraft, or which involve NASA to any degree. All activities using animal subjects conducted under a contract, grant, cooperative agreement, memorandum of understanding, or joint endeavor agreement entered into by NASA and another Government agency, private entity, non-Federal public entity, or foreign entity are included within the scope of this rule.

§ 1232.102 Policy.

(a) It is NASA policy to require its laboratories and the institutions performing NASA-supported activities using animal subjects to comply with the Animal Welfare Act of 1966 (Pub. L. 89-544), as amended (Pub. L. 91-579, Pub. L. 94-279, and Pub. L. 99-198), 7 U.S.C. 2131 et seq., and 39 U.S.C. 3001, and with the regulations promulgated

thereunder by the Secretary of Agriculture (9 CFR subchapter A parts 1, 2, 3, and 4) pertaining to the care, handling, and treatment of animal subjects held or used for research, testing, teaching, or other activities supported by the Federal government. Investigators shall follow the guidelines described in the National Institutes of Health (NIH) Publication No. 85-23 (Rev. 1985), "Guide for the Care and Use of Laboratory Animals" (the Guide) or subsequent revisions. Attention is called to the U.S. Government "Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training" on pp. 81-83 of the Guide. In order to implement these guidelines and principles, investigators will comply with the revised Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (hereinafter referred to as PHS Policy) effective November 1, 1986.¹

(b) This rule authorizes NASA to have the same authority for NASA-supported programs as that delegated to PHS by the PHS Policy, including the functions and responsibilities of the Animal Care and Use Committees (ACUC's).

(c) All research supported by NASA that involves activities using animal subjects shall be conducted under protocols that conform to this rule and that are reviewed and approved as prescribed in this rule.

§ 1232.103 Definitions.

The following definitions of terms comply with the PHS Policy and apply to the conduct of all NASA activities related to the care and use of animal subjects.

(a) *Activity* includes research, testing of hardware for animal use, flight experimentation, and any other tasks involving the use of animal subjects.

(b) *Animal* is any live vertebrate animal.

(c) *Animal Care and Use Committee* (ACUC) is the committee established at

¹Available from the Office of Protection from Research Risks (OPRR), National Institutes of Health, 9000 Rockville Pike, Bldg. 31, Room 5B59, Bethesda, MD 20892, Telephone 301-496-7005.

each institution and NASA field installation involved in research with animal subjects. It is responsible for evaluating the care and use of animal subjects at the facility and for ensuring that the care and use of animal subjects at the facility is in compliance with this rule and PHS Policy.

(d) *Authorized NASA Official* is the Director, Life Sciences Division, NASA Headquarters, or designee, who is the NASA Administrator's representative and is responsible for all NASA activities involving animal subjects. This individual is responsible for implementation of the provisions of this rule and for ensuring that agency programs involving animal subjects comply fully with all applicable laws, regulations, and guidelines.

(e) *Field Installation Director* is the Director of a NASA Field Installation, or designee, who is the institutional official responsible for the care and use of animal subjects in research conducted at that field installation and for ensuring compliance with this rule at that field installation.

(f) *Investigator* is any person who uses or proposes to use live animal subjects in NASA-supported activities, e.g., receives funds, salaries, or support under a grant, award, agreement, contract, or direct employment by NASA, or the use of any NASA facilities, aircraft, or spacecraft for the purpose of carrying out research, tests, or experiments using animal subjects.

(g) *PHS Assurance* is a document prepared by an awardee institution assuring its compliance with PHS Policy.

(h) *Research of Flight Program Manager* is the NASA Headquarters manager of each program in which NASA has a manifest interest.

(i) *Supported* pertains to activities either funded in part or in whole by NASA or an approved activity that is not funded by NASA but that utilizes NASA facilities, including spacecraft and aircraft.

(j) *Veterinarian* is the NASA attending veterinarian, a person who has graduated from a veterinary school accredited by the American Veterinary Medical Association's Council on Education or has a certificate issued by the American Veterinary Medical Association's Education Commission for For-

eign Veterinary Graduates, has received training and/or experience in the care and management of the species being attended, and who has direct or delegated authority and responsibility for activities involving animal subjects at the NASA field installation.

§ 1232.104 Implementation procedures by non-NASA institutions.

(a) *Proposal Information.* No animal subjects may be utilized unless a proposal justifying and describing their use is submitted to NASA for approval. The required proposal information is outlined in the PHS Policy (IV.D.1.a.-e.).

(b) *Proposal Approval by the Institutional ACUC.* Before a proposal for research involving the use of animal subjects will be considered for NASA support, the NASA Headquarters Research or Flight Program Manager must receive a statement that the research has been reviewed in accordance with the PHS Policy (IV.C.) and approved by the appropriate ACUC at the participating institution.

(c) *Proposal Approval for Flight Experiments.* In addition to the institution's ACUC review, activities involving animal subjects to be flown on NASA spacecraft will be subject to review and approval by the Ames Research Center (ARC) ACUC. The ARC ACUC will submit each evaluation report to the ARC Director who will transmit the report with his/her recommendation to the Authorized NASA Official, NASA Headquarters. Animal activities to be flown onboard NASA manned spacecraft may also be subject to review by the Human Research Policy and Procedures Committee (HRPPC) at the Johnson Space Center (JSC). Animal activities utilizing the facilities of any NASA field installation are also subject to approval of that field installation's ACUC (§ 1232.105(d)).

(d) *Institutions with PHS Assurance on File.* The institution, by an approved or provisionally acceptable Assurance on file at the NIH Office for Protection from Research Risks (OPRR), Department of Health and Human Services (HHS), assures NASA that it will comply with the PHS Policy. The Assurance file number must be included in

the research proposal submitted to NASA.

(e) Institutions with no PHS Assurance on File. Proposals from institutions without an approved Assurance on file with the NIH OPRR will first be peer-reviewed for scientific merit. If the proposed research is deemed worthy of support, NASA will arrange for a special Assurance to be negotiated by the Director, Life Sciences Division, NASA Headquarters. The arrangements for a special Assurance review by NIH should be undertaken in consultation with the NASA representative to the Interagency Research Animal Committee (IRAC) and will be handled on a case-by-case basis.

(f) Foreign institutions must comply with the PHS Policy (see Section II Of PHS Policy) and this rule before being supported by NASA for any activities involving animal subjects.

§ 1232.105 Implementation procedures by NASA field installations.

(a) *Proposal Information.* The information required for proposals involving the use of animal subjects is identical to that described in § 1232.104(a).

(b) *Proposal Approval by the NASA ACUC.* Before a proposal for research involving the use of animal subjects will be considered for NASA support, the NASA Headquarters Research or Flight Program Manager must receive a statement that the research has been reviewed in accordance with PHS Policy (IV.C.) and approved by the ACUC at the appropriate field installation.

(c) *Proposal Approval for Flight Experiments.* In addition to the Field Installation ACUC review, activities involving animal subjects to be flown on NASA spacecraft will be subject to review and approval by the ARC ACUC. The ARC ACUC will submit each evaluation report to the ARC Director who will transmit the report with his/her recommendation to the Authorized NASA Official, NASA Headquarters. Animal activities to be flown onboard NASA manned spacecraft may also be subject to review by the HRPPC at JSC.

(d) *Approval for Use of Field Installation Facilities.* The NASA Field Installation ACUC will review and approve or disapprove those parts of proposals that call for the use of their facilities

to conduct any activity involving animal subjects (e.g., Kennedy Space Center or ARC Dryden facilities used to support experiments using animal subjects). The ACUC will submit each evaluation report to the Field Installation Director who will transmit the report with his/her recommendation to the Authorized NASA Official, NASA Headquarters.

(e) *NASA Animal Care and Use Committees.* (1) The Director of each NASA Field Installation that is involved in animal research activities will establish an ACUC to ensure compliance with the policies and provisions of this rule. The membership of the ACUC shall be in accordance with PHS Policy.

(2) The NASA Field Installation ACUC's will review and approve or disapprove all proposals using animal subjects. In accordance with the PHS Policy (IV.C.), the ACUC will submit each report to the Field Installation Director who will, upon request, transmit the report with his/her recommendation to the Authorized NASA Official, NASA Headquarters.

(3) NASA ACUC's have the authority to approve, disapprove, or require changes to be made in those components of proposals involving the care and use of animal subjects that are submitted by NASA investigators. All decisions shall be based on the response of a majority of a quorum of the members. A minority opinion including abstentions should be recorded; this record should include a justification for the opinion.

(4) The ACUC shall conduct continuing review of proposals at appropriate intervals as determined by the ACUC, but not less than once every 3 years.

(5) Proposals that have been approved by the ACUC may be subject to further appropriate review by the Authorized NASA Official, NASA Headquarters. However, the official may not approve those sections of a proposal related to the care and use of animal subjects if they have not been approved by the ACUC.

(6) Once experimental procedures are approved, no substantial changes can be made unless a formal request with

appropriate justification for such a request is submitted to and approved by the appropriate ACUC. If the experiment involves exposure of the flight crew to the animal subjects, the HRPPC at JSC must review and approve the proposed modifications. Copies of ACUC approval of the proposed modifications shall be submitted to the Field Installation Director who will, upon request, transmit the report to the Authorized NASA Official, NASA Headquarters.

(7) Other functions of the field installation ACUC include:

(i) Reviewing at least once every 6 months the field installation's program for humane care and use of animals, using the Guide as a basis for evaluation;

(ii) Inspecting at least once every 6 months all of the field installation's animal facilities (including satellite facilities), using the Guide as a basis for evaluation;

(iii) Preparing reports of the ACUC evaluations conducted as required by § 1232.105 (e)(7)(i) and (ii), and submitting the reports to the Field Installation Director. (Note: the reports shall be updated at least once every 6 months upon completion of the required semiannual evaluations and shall be maintained by the field installation and made available to the Authorized NASA Official upon request. The reports must contain a description of the nature and extent of the field installation's adherence to the Guide and this rule and must identify specifically any departures from the provisions of the Guide and this rule, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, consistent with PHS Policy, and, in the judgment of the ACUC and the Field Installation Director, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule for correcting each deficiency.)

(iv) Reviewing concerns involving the care and use of animals at the field installation;

(v) Making recommendations to the Field Installation Director regarding any aspect of the field installation's animal program, facilities, or personnel training.

(f) *NASA Assurances.* Each NASA field installation involved in activities using animal subjects must assure that its programs and facilities have been evaluated and accredited by the American Association for the Accreditation of Laboratory Animal Care (AAALAC). Written assurance of compliance with the provisions of the PHS Policy and this rule is also required from NASA field installations involved in animal activities before approval of any such activity. This Assurance should follow the sample PHS Assurance format shown on pages 19–26 of the PHS Policy and must be submitted by the Field Installation Director to the Authorized NASA Official. The Assurance is subject to renewal every 5 years.

(g) *Recordkeeping Requirements.* (1) Each NASA field installation involved in activities using animal subjects shall maintain:

(i) An Assurance of compliance with PHS Policy and this rule (§ 1232.105 (f));

(ii) Minutes of ACUC meetings, including records of attendance, activities of the committee, and committee deliberations;

(iii) Records of applications, proposals, and proposed significant changes in the care and use of animals and whether ACUC approval was given or withheld;

(iv) Records of semiannual ACUC reports and recommendations (including minority views) as forwarded to the Field Installation Director;

(v) Records of AAALAC accreditation; and

(vi) The Field Installation's Animal Users Guide and Animal Care Facility Management Manual. The Field Installation Animal Users Guide and Animal Care Facility Management Manual should be revised at appropriate intervals.

(2) All records shall be maintained for at least 3 years; records that relate directly to applications, proposals, and proposed significant changes in ongoing activities reviewed and approved by the ACUC shall be maintained for the

duration of the activity and for an additional 3 years after completion of the activity. All records shall be furnished upon request to the Authorized NASA Official.

(h) *Reporting Requirements.* For each NASA field installation involved in activities using animal subjects:

(1) Statements of ACUC approval of research proposals, ACUC evaluation reports of flight experiment proposals and of experiment proposals utilizing field installation facilities, and the field installation's Assurance of compliance shall be submitted in the manner prescribed in §§1232.104(c) and 1232.105 (b), (c), (d), and (f).

(2) At least once every 12 months, the ACUC, through the Field Installation Director, shall report in writing to the Authorized NASA Official:

(i) Any change in the field installation's program or facilities that would affect the AAALAC accreditation status;

(ii) Any change in the description of the field installation's program for animal care and use;

(iii) Any changes in the ACUC membership;

(iv) Notice of the dates that the ACUC conducted its semiannual evaluations of the field installation's program and facilities and submitted the evaluations to the Field Installation Director;

(v) A statement that the field installation has no changes to report as specified in §1232.105(h)(2) (i), (ii), or (iii) of this rule, if there are no changes.

(3) The ACUC, through the Field Installation Director, shall promptly provide the Authorized NASA Official with a full explanation of the circumstances and actions taken with respect to:

(i) Any serious or continuing non-compliance with this rule and PHS Policy;

(ii) Any serious deviation from the provisions of the Guide; or

(iii) Any suspension of an activity by the ACUC.

(4) Reports filed under §1232.105 (h) of this rule shall include any minority views filed by members of the ACUC.

(5) A copy of the U.S. Department of Agriculture (USDA) Annual Report will be furnished to the Authorized NASA Official.

§ 1232.106 Management authority and responsibility.

(a) *Authorized NASA Official.* The Authorized NASA Official is the NASA Administrator's representative and is responsible for all NASA activities involving animal subjects. This individual is responsible for implementation of the provisions of this rule and for ensuring that agency programs involving animal subjects comply fully with all applicable laws, regulations, and guidelines.

(b) *Field Installation Director.* The Field Installation Director is responsible for and has the authority to:

(1) Sign the field installation's Assurance, making a commitment on behalf of the field installation that the requirements of the PHS Policy and this rule will be met in all field installation activities involving animal subjects;

(2) Create and oversee the functioning of the field installation ACUC;

(3) Decide and administer sanctions in cases of noncompliance with this rule;

(4) Fulfill the reporting requirements assigned to this individual in §1232.105(h); and

(5) Sign the annual USDA report.

(c) *NASA Field Installation(s) ACUC Responsibility.* Each NASA Field Installation ACUC is responsible to its Field Installation Director for the activities described in §§1232.104(c) and 1232.105 (b), (c), (d), (e) and (h).

(d) *Research or Flight Program Manager Responsibility.* The Research or Flight Program Manager is responsible for ascertaining the presence of the required PHS Assurance file number for proposals involving animal subjects received from non-NASA institutions, and a statement of ACUC review and approval of all NASA and non-NASA proposals involving animal subjects. No awards for activities involving animal subjects can be made without this documentation [see §§1232.104 (b) and (d) and 1232.105(b)].

(e) *NASA Veterinarian(s) Responsibility.* NASA veterinarian(s) have direct or delegated authority and responsibility for activities involving animal subjects at their field installation. Such authority and responsibilities shall include recommending approval or disapproval of procedures involving

animal subjects as a member of the ACUC, continual monitoring of these activities, surveillance of the health and condition of animal subjects, and reporting any observed deviations from approved procedures involving animal subjects to the Field Installation Director and the ACUC. In the case of deviation from ACUC-approved practices or procedures, the veterinarian shall have the authority to immediately halt such procedures until they are reviewed and resolved by the ACUC. In cases of a conflict concerning animal usage by an investigator that cannot be resolved between him/her and the veterinarian, the matter may be brought to the attention of the Field Installation ACUC for review and recommendation for action as set forth in this rule. Whereas the performance of the veterinarian's duties can be delegated to other qualified individuals, the ultimate responsibility rests with the veterinarian. This responsibility extends not only to the Animal Care Facility (ACF), but also to other locations where animal subjects are used.

Other specific areas of responsibility and authority vested in the veterinarian are:

(1) *Entry of personnel into the ACF.* The veterinarian has the responsibility to develop access procedures to the ACF and submit them to the ACUC for approval.

(2) *Personnel Training.* The veterinarian will participate in the training of personnel in the handling of animal subjects and in specimen sampling procedures.

(3) *Animal Training.* The veterinarian will monitor all schedules and procedures involving the training and acclimation of animal subjects.

(4) *Surgery and Surgical Procedures.* The veterinarian will monitor all surgical procedures and verify that the principles of the Guide with regard to aseptic surgery are employed. Post-surgical recovery procedures are included. If necessary, training will be provided by the veterinarian to bring procedures conducted by investigators to the level of these standards.

(5) *Veterinary Medical and Engineering Procedures.* The veterinarian will monitor all veterinary medical and engineering procedures performed on ani-

mal subjects and verify their appropriateness. The veterinarian will actively participate in identifying and/or establishing the design requirements and adequacy of animal facilities for ground and spaceflight-related activities.

(f) *NASA Representative to the Inter-agency Research Animal Committee (IRAC).* The NASA representative to the IRAC will obtain information of all cases in which an institution's Assurance has been revoked by the PHS. The NASA IRAC representative will notify NASA ACUC's, Field Installation Directors, the Authorized NASA Official, and all Headquarters Research and Flight Program Managers so that they can determine which NASA awards involving the use of animal subjects are affected and can take appropriate sanctions.

§ 1232.107 Sanctions.

(a) *Non-NASA Institutions.* Principal investigators not employed by NASA whose activities are supported by NASA but whose activities using animal subjects are restricted to non-NASA facilities shall be subject to the control of their institution's ACUC and responsible institutional official. Notification of noncompliance with this rule shall be made either as described in § 1232.106(f) or by the non-NASA institution to the Director of the NASA Field Installation through which the activity has been supported and to the Authorized NASA Official. Any continued noncompliance may be caused for termination of funding or support.

(b) *NASA Field Installations.* (1) Inappropriate procedures on animal subjects by NASA principal investigators shall be halted by the NASA Field Installation Veterinarian or line management and brought to the attention of the ACUC if the issue cannot be immediately resolved. The ACUC will review the activity and report any noncompliance with this rule to the Field Installation Director. Principal investigators not employed by NASA, whose activities using animal subjects are performed in NASA facilities, aircraft, or spacecraft, are subject to similar action. Such noncompliance will be cause

for sanctions. The principal investigator can contest, in writing, these decisions to the ACUC.

(2) The ACUC as the agent of the Field Installation Director may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, PHS Policy requirements, or this rule.

(3) Any suspension or termination of approval will include a statement of the reasons for the action and will be promptly reported to the principal investigator and the appropriate Field Installation Director. In the case of investigators from non-NASA institutions, notification should be sent to the investigator, the appropriate institution, and the Director of the Field Installation through which the activity has been supported. If the ACUC suspends an activity involving animal subjects, the Field Installation Director in consultation with the ACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to the Authorized NASA Official, NASA Headquarters. If an ACUC recommends disapproval suspension, termination, or conditional approval of an activity, the principal investigator will be given the opportunity to ask for reconsideration of the decision in person and/or in writing to the appropriate NASA ACUC.

(4) If, after notification of the Field Installation Director and an opportunity for correction, such deficiencies or deviations remain uncorrected, the ACUC will notify (in writing) the Authorized NASA Official, NASA Headquarters, who is then responsible for all corrective action to be taken.

PART 1240—INVENTIONS AND CONTRIBUTIONS

Subpart 1—Awards for Scientific and Technical Contributions

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AUTHORITY: Section 306 of the National Aeronautics and Space Act of 1958, as amended (42 U.S.C. 2458), and the Federal Technology Transfer Act of 1986, sec. 12, 15 U.S.C. 3710b(1).

SOURCE: 67 FR 31120, May 9, 2002, unless otherwise noted.

Subpart 1—Awards for Scientific and Technical Contributions

§ 1240.100 Purpose.

This subpart prescribes procedures for submitting applications for monetary awards to the Administrator of NASA for scientific and technical contributions which have significant value in the conduct of aeronautical and space activities pursuant to 42 U.S.C. 2458, and establishes the awards program consistent with the Federal Technology Transfer Act of 1986, section 12, 15 U.S.C. 3710b(1).

§ 1240.101 Scope.

This subpart applies to any scientific or technical contribution, whether or not patentable, which is determined by the Administrator after referral to the Inventions and Contributions Board to have significant value in the conduct of aeronautical and space activities for which an application for award has been submitted to NASA under 42 U.S.C. 2458.

§ 1240.102 Definitions.

As used in this subpart:

(a) *Administrator* means the Administrator of the National Aeronautics and Space Administration.

(b) *Board* means the NASA Inventions and Contributions Board.

(c) *Chairperson* means the Chairperson of the NASA Inventions and Contributions Board.